

of estrogenic steroids calculated as not more than 0.55 mg. of sodium estrone sulfate per tablet.

LABEL, IN PART: (195-bottle lot) "Cogenat 0.625 mg. Conjugated Estrogens" and (1-bottle and 19-bottle lots) "Cogenat 1.25 mg. Conjugated Estrogens."

NATURE OF CHARGE: Adulteration, Section 501 (c), the strength of the article in each of the two lots differed from that which it was represented to possess, namely, 0.625 mg. and 1.25 mg., respectively, of conjugated estrogens expressed as sodium estrone sulfate.

Misbranding, Section 502 (a), the label statements on the two lots of the article, namely, "Each tablet contains: Conjugated Estrogens * * * 0.625 mg. [or "1.25 mg."] expressed as Sodium Estrone Sulfate" were false and misleading as applied to an article containing less than the stated amounts of estrogenic steroids calculated as sodium estrone sulfate.

DISPOSITION: July 31, 1951. Default decree of condemnation and destruction.

3512. Adulteration and misbranding of Conjugens tablets and Conjugestoral tablets (conjugated estrogens). U. S. v. 2 Bottles, etc. (and 1 other seizure action). (F. D. C. Nos. 30767, 39872. Sample Nos. 23103-L, 23105-L.)

LIBELS FILED: March 8 and 27, 1951, District of New Jersey.

ALLEGED SHIPMENT: On or about November 20 and 22 and December 4, 1950, by Success Chemical Co., Inc., from Brooklyn, N. Y.

PRODUCT: 2 1,000-tablet bottles and 1 bottle containing 600 tablets of *Conjugens* and 1 1,000-tablet bottle of *Conjugestoral* at East Orange, N. J., and 1 bottle containing approximately 350 *Conjugens* tablets at Bloomfield, N. J.

Analyses of two samples taken from the shipments of *Conjugens* showed the total amount of estrogens actually present in the samples to be equivalent to 0.56 mg. and 0.78 mg., respectively, of sodium estrone sulfate per tablet. Analysis of a sample of the *Conjugestoral* tablets showed the total amount of estrogens actually present in the sample to be equivalent to 0.35 mg. of sodium estrone sulfate per tablet.

LABEL, IN PART: "Tablets Conjugens (Conjugated Estrogens) * * * Distributed by Success Chemical Co., Inc., Brooklyn, New York" and "Tablets Conjugestoral (Conjugated Estrogens) * * * Distributors Corby-Franklin Associates New York, N. Y."

NATURE OF CHARGE: Adulteration, Section 501 (c), the strength of the articles differed from that which they were represented to possess, namely, 1.25 mg. of estrogens in their naturally occurring water-soluble conjugated form expressed as sodium estrone sulfate.

Misbranding, Section 502 (a), the label statement "Each tablet contains 1.25 mgm. of Estrogens in their naturally occurring water-soluble conjugated form expressed as sodium estrone sulfate" was false and misleading as applied to the articles, which contained less than the stated amount of estrogens.

DISPOSITION: July 11 and 12, 1951. Default decrees of condemnation. The court ordered that the lot seized at Bloomfield be destroyed and that the lots seized at East Orange be delivered to the Food and Drug Administration.

3513. Adulteration and misbranding of Estrotron. U. S. v. 40 Bottles * * *. (F. D. C. No. 30930. Sample No. 29728-L.)

LIBEL FILED: April 24, 1951, Western District of Washington.

ALLEGED SHIPMENT: On or about January 2, February 2, and March 9, 1951, by the Pitman-Moore Co., from Indianapolis, Ind.

PRODUCT: 40 bottles of *Estrotron* at Seattle, Wash. Examination showed that the product contained not more than 1.18 milligrams of estrogenic ketosteroids per cubic centimeter.

LABEL, IN PART: (Bottle and carton) "10 cc. Size * * * *Estrotron*, 2 mg. (20,000 I. U.) per cc. in Peanut Oil. A highly purified estrus producing extract from the urine of pregnant mares, consisting primarily of estrone with smaller quantities of naturally occurring estrogens, dissolved in Peanut Oil and standardized to 20,000 I. U. of activity per cc."

NATURE OF CHARGE: Adulteration, Section 501 (c), the strength of the article differed from that which it was represented to possess, namely, 2 milligrams of estrogenic ketosteroids per cubic centimeter.

Misbranding, Section 502 (a), the following statements in the labeling of the article were false and misleading as applied to an article which contained less than the declared amount of estrogenic ketosteroids per cubic centimeter: (Bottle and carton label) "* * * *Estrotron*, 2 mg. (20,000 I. U.) per cc. * * * consisting primarily of estrone with smaller quantities of naturally occurring estrogens * * * standardized to 20,000 I. U. of activity per cc. * * *" and (accompanying leaflet entitled "*Estrotron*") " * * * containing 2 mg. of estrogenic substance per cc. equal in estrogenic activity to 20,000 I. U. per cc."

DISPOSITION: June 18, 1951. Default decree of condemnation and destruction.

3514. Adulteration and misbranding of Premestrone (conjugated estrogens).

U. S. v. 197 Bottles * * *. (F. D. C. No. 30734. Sample No. 10119-L.)

LIBEL FILED: April 9, 1951, Eastern District of Michigan.

ALLEGED SHIPMENT: On or about January 9, 1951, by the Doctors' Mutual Service Co., from Glendale, Calif.

PRODUCT: 197 bottles of *Premestrone* (conjugated estrogens) at Detroit, Mich. Examination showed that the total amount of estrogens actually present in the article was equivalent to 0.22 mg. of sodium estrone sulfate per tablet.

LABEL, IN PART: "*Premestrone* 0.4 mg. 90 Tablets Estrogenic Substances (Water Soluble). Also Known As Conjugated Estrogens (Equine). * * * Formulated And Distributed By Specific Bio-Chemicals Glendale, California."

NATURE OF CHARGE: Adulteration, Section 501 (c), the strength of the article differed from that which it was represented to possess, namely, 0.4 mg. of estrogens in their water-soluble form expressed as sodium estrone sulfate.

Misbranding, Section 502 (a), the label statement "Each tablet contains 0.4 mg. of estrogens in their water soluble form expressed as sodium estrone sulfate" was false and misleading as applied to an article which contained 0.22 milligram of sodium estrone sulfate per tablet.

DISPOSITION: June 12, 1951. Default decree of condemnation and destruction.

3515. Adulteration and misbranding of Hemotene tablets. U. S. v. 148 Bottles, etc. (F. D. C. No. 31181. Sample No. 16763-L.)

LIBEL FILED: June 7, 1951, Southern District of California; amended libel filed June 28, 1951.